IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHN ALBERICI, individually and on behalf of all others similarly situated **v.** **RECRO PHARMA, INC., GERALDINE A. HENWOOD, STEWART MCCALLUM**, and **JOHN HARLOW**	**CIVIL ACTION** **NO. 18-2279**

MEMORANDUM RE SECOND MOTION TO DISMISS AMENDED COMPLAINT

Baylson, J. **March 1, 2021**

I. Introduction

In the present case, Plaintiff alleges that Recro Pharma Inc. concealed concerns about a drug's efficacy and manufacturing quality control. As alleged, Recro's investors learned of these issues only after the FDA refused to approve the drug — intravenous meloxicam ("IV meloxicam") — causing the stock value of Recro to plummet. Plaintiff sued Recro and several of its executives, claiming that they perpetrated a fraud on a class of investors in violation of the Securities Exchange Act of 1934.

This Court has examined Plaintiff's claims once before: it granted Defendants'[1] motion to dismiss on the grounds that Plaintiff failed to sufficiently plead a culpable mental state for the alleged wrongdoing. ECF 47, Alberici v. Recro Pharma, Inc., No. 18-2279, 2020 WL 806719 (E.D. Pa. Feb. 14, 2020) (Baylson, J.) ("Alberici I"). Simultaneously, however, the Court held

[1] The term "Defendants" encompasses Recro and "Individual Defendants" — Geraldine Henwood, Stewart McCallum, and John Harlow.

that Plaintiff had satisfied its burdens in pleading the materiality of the misrepresentations and loss causation. The Court declined to rule on each statement's falsity or actionability.

Plaintiff filed its Second Amended Complaint, ECF 50 ("SAC"); it argues it has now met the Court's concerns. Additionally, since Alberici I and the filing of the SAC, the FDA has approved IV meloxicam. Defendants argue this update merits reconsideration of the Court's prior findings of materiality and loss causation.

The Court agrees with Plaintiff. The SAC satisfies the Court's prior concerns regarding insufficient allegations for scienter and the statements' falsity. While the FDA's subsequent approval of the drug may be relevant to loss causation, it does not fundamentally alter the Court's prior conclusions. The Court therefore DENIES Defendants' Second Motion to Dismiss.

II. Factual Allegations[2]

The Court takes the allegations in the SAC as true and draws all reasonable inferences in favor of Plaintiff, as is required at the motion to dismiss stage. Phillips v. Cty. of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008). Additionally, as the Court is "faced with a Rule 12(b)(6) motion to dismiss a § 10(b) action," it will consider information in "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322 (2007).[3]

Plaintiff's Second Amended Complaint contains many of the same factual allegations as this Court previously discussed in Alberici I. The Court therefore incorporates Alberici I's discussions regarding development of IV meloxicam and the FDA's initial review of the drug. See 2020 WL 806719, at * 1–3 (discussing "Factual Allegations"). Since Alberici I, Plaintiff has

[2] For ease of reference, this opinion will cite to filed documents using the page numbers printed on ECF (i.e. the PDF page number) where appropriate, even if they have internal pagination.
[3] See infra Section IV (discussing Judicial Notice).

revised its allegations relevant to scienter and list of allegedly actionable misstatements. The Court will discuss both. In addition, the Court takes judicial notice that the FDA approved IV meloxicam since the filing of the SAC. The FDA approved the drug for both hard- and soft-tissue uses on February 20, 2020. ECF 51 ("Defs.' Br.") at 186–91 (Def.'s Ex. L); see also infra Section IV (Judicial Notice).

a. Scienter: Defendants' Awareness of KOL Concerns

In preparing to launch IV meloxicam, Recro relied on 200–300 Key Opinion Leaders ("KOLs"), medical professionals and physicians who provide subject matter expertise, to shape its decision-making in marketing, research, and development. SAC at ¶¶ 32–34.

Plaintiff's confidential witness ("CW1") was employed in senior Medical Affairs roles throughout the class period; he and his team "frequently communicated" with KOLs and reported their feedback to Recro leadership. Id. at ¶¶ 35, 36. CW1 reported to Individual Defendants that KOLs did not intend to use for soft-tissue procedures and that they believed Recro's overseas manufacturing oversight of IV meloxicam was insufficient. Id. at ¶ 42.[4]

- Soft-Tissue Use: "[A]pproximately 75% of soft-tissue KOLs who had the ability to drive protocols in medical institutions . . . did not intend to use IV meloxicam in their procedures because of the trial data." Id. at ¶ 69. And "a significant majority" of all KOLs did not intend to use IV meloxicam in soft-tissue procedures based on the perceived weakness of the clinical trial data. Id. at ¶ 66. By contrast, 99.9% of KOLs "were convinced that IV meloxicam should be used in orthopedic (or hard tissue) procedures." Id.

[4] These conversations and reports took place between June 2017 to May 2018, as they allegedly occurred during CW1's employment at Recro during those months.

- Manufacturing Oversight: "[A]pproximately 30% of KOLs" were concerned about Recro's plan to manufacture IV meloxicam overseas in Ireland, including concerns about inadequate supervision. Id. at ¶¶ 59, 61. Recro had only one employee overseeing IV meloxicam's manufacturing and packaging; he lived in Pennsylvania and commuted to Ireland part-time for this role. Id. at ¶ 61.

i. Soft-Tissue Use Concerns

CW1 personally reported to McCallum and Harlow that KOLs "frequently" opined that "the trial data was not compelling enough for them to use the drug in soft-tissue procedures" and that "KOL reluctance was especially strong among colorectal surgeon KOLs, who were also concerned about bleeding risks." Id. at ¶ 72. CW1 and his team "frequently reported" this information to McCallum and Harlow and knew that it was "discussed by McCallum and Harlow" as well. Id. at ¶ 73.

Leadership Team Meetings: CW1 attended Recro's weekly Leadership Team meetings (in-person or remotely), held in a conference room at Recro's headquarters in Malvern, Pennsylvania, from June 2017 through May 2018. Id. at ¶¶ 35, 39. Individual Defendants were all members of the Leadership Team. Id. at ¶ 40. McCallum and Harlow "consistently attended" the meetings, and, while she "did not frequently attend," Henwood "always received reports of these meetings" from the other Individual Defendants. Id. At these meetings, CW1 and his Medical Affairs teams reported that KOLs had concerns for IV meloxicam, including about "oversight of manufacturing in Ireland, the lack of safety data on bleeding risks for IV meloxicam, and the fact that KOLs were not intending to use IV meloxicam in their soft-tissue procedures because the drug's efficacy clinical trial data was not compelling." Id. at ¶ 42.

Feedback Reports: CW1 compiled KOL feedback reports and submitted them to McCallum; McCallum then prepared summaries for Henwood based on his reading of those

reports and with CW1's input. Id. at ¶¶ 74, 75. McCallum presented these reports at monthly meetings in Malvern with Henwood (and with Harlow in attendance). Id. at ¶ 75. CW1 personally saw that these reports "included the information that KOLs did not want to use IV meloxicam for soft-tissue procedures." Id.

Advisory Board meetings: Recro hosted quarterly Advisory Board meetings, which featured a panel of approximately twelve orthopedic and colorectal KOLs (hard- and soft-tissue specialists, respectively) providing expert opinions on IV meloxicam. Id. at ¶ 76. CW1 personally attended four of these meetings in 2017 and 2018 (at least one of which took place in the Grand Hyatt at the Dallas-Fort Worth International Airport) that McCallum planned and both McCallum and Harlow attended. Id. At each of these Advisory Board meetings that CW1 attended, the colorectal KOLs "made their opinions clear to McCallum and Harlow . . . that the trial data did not convince the majority of them to start using IV meloxicam in their soft-tissue procedures" and it would "be a very hard sell" to include IV meloxicam in their institutions' treatment protocols for soft-tissue procedures. Id. at ¶¶ 76, 77. "[M]any of the KOLs on the Advisory Board question[ed] McCallum and Harlow as to why the Company was not seeking FDA approval for just the hard-tissue indication." Id. at ¶ 77. Following these meetings, CW1 helped McCallum prepare executive summaries for Henwood; these "reported that the majority of [colorectal] KOLs did not intend to use IV meloxicam in their procedures." Id. at ¶ 79.

Sales Strategies: Based on KOL feedback, Recro assumed the sales strategy of prioritizing IV meloxicam sales to orthopedic/hard-tissue uses and away from soft-tissue uses. Id. at ¶ 80. In designing sales representative training, Recro's sales leadership team advised "focusing the team on orthopedic procedures and staying away from recommending the product for soft-tissue

purposes." Id. CW1 attended these meetings and recalled McCallum and Harlow's participation in them. Id. He also recalled Henwood attended some but not all sales strategy meetings. Id.

ii. Manufacturing Oversight Concerns

Approximately 30% of KOLs expressed concern to CW1 about IV meloxicam being manufactured overseas, foreseeing that its manufacture and packaging processes in Ireland could "sink [FDA] approval of the drug." Id. at ¶ 59. Specifically, those KOLs worried that Irish manufacturing plants may not satisfy FDA pre-approval plant inspections, id., and that Recro's manufacturing oversight team was understaffed (it had only one overseeing employee, who lived in Pennsylvania and did not provide full-time onsite services). Id. at ¶ 61.

CW1 and his team informed Individual Defendants of these manufacturing oversight concerns through the weekly Leadership Team meetings in Malvern and through written reports. Id. at ¶ 64.

b. Actionability: Recro's Alleged Misrepresentations

Based on the above, Plaintiff alleges that Defendants were aware of KOLs' warnings that IV meloxicam was not suitable for soft-tissue procedures and that Recro's overseas manufacturing had insufficient oversight. Id. at ¶¶ 65, 81. But the public was not made aware of these concerns until May 24, 2018, when Recro issued a press release regarding the FDA's reasons for denying IV meloxicam's NDA. Id. at ¶¶ 6, 7.

Plaintiff identifies eighteen materially false and misleading statements between July 17, 2017 and May 23, 2018 (the "Challenged Statements"), in which it contends that Defendants misled investors regarding the KOLs' concerns. See id. at ¶¶ 82–102. For the purposes of the present motion, these statements fall into roughly four categories.

Target Opportunity Statements (SAC ¶¶ 82–84, 86–89, 91–93, 97, 100, 101). These statements focus on soft-tissue uses as a marketing "target opportunity" or "target procedure" —

or use similar language regarding planned growth in the soft-tissue market[5] — without mentioning KOLs' concerns about IV meloxicam's unsuitability for soft-tissue markets.

Market Frequency Statements (SAC ¶¶ 94, 98, 102). These statements tout health care professional surveys saying that about 30% of professionals planned to use IV meloxicam in their surgical cases. They do not mention KOLs' concerns about IV meloxicam's unsuitability for soft-tissue markets.

Manufacturing Oversight Statement (SAC ¶ 96). This statement referred to Recro's manufacturing "oversight by our internal managers" in the plural. Plaintiff alleges there was only one internal manager tasked with manufacturing oversight.

SOX Certification (SAC ¶ 95). This statement certified as true the statements in Recro's March 2, 2018 Form 10-K (which contained the language Manufacturing Oversight Statement) pursuant to the Sarbanes-Oxley Act. Plaintiff alleges that the certification itself is a misrepresentation.

III. Procedural History

John Alberici initially filed a complaint against Recro and several individual defendants in May 2018. ECF 1. Pursuant to the PSLRA, this Court accepted briefing regarding appointment of the lead plaintiff and lead counsel, naming Plaintiff (a group of investors including Alberici) and Plaintiff's attorneys as lead counsel. ECF 21. Plaintiff filed its First Amended Complaint in December 2018. ECF 26.

[5] Example language includes "potential to be an attractive non-opioid alternative" for "following abdominoplasty surgery," SAC ¶ 86; "core procedures" or "core target procedures" include those performed by "gastrointestinal [or] colorectal surgeons," id. at ¶¶ 93, 97, 101; and "procedures conducted by [GI colorectal] surgeons represent a primary opportunity," id. at ¶ 100.

The Court next reviewed the parties' briefing on Defendants' First Motion to Dismiss, ECF 31–33, 41, 43, and oral arguments on the same, ECF 39. In the corresponding opinion, the Court granted Defendants' motion and dismissed the First Amended Complaint without prejudice on February 14, 2020. Alberici I (at ECF 47).

In doing so, the Court ruled that Plaintiff had satisfied its burden on four of the six elements required for a claim under Section 10(b) — including loss causation and materiality of the challenged misrepresentations/omissions — but it had failed (1) to satisfy the PLSRA's heightened pleading burdens for scienter and (2) to consistently allege falsity and actionability of the challenged statements.

Regarding scienter, the Court wrote:

> Viewed "holistically," these allegations do not suggest a strong inference of scienter. Without further detail as to exactly what CW1 communicated regarding the KOLs' efficacy concerns, and to whom, and when/how often, it is impossible to evaluate the plausibility of competing inferences, such as the possibility that the percentage of KOLs who expressed concerns was insignificant, or that further clinical study would alleviate the concerns, or that reasonable KOLs differed on the efficacy question. Said differently, the Court is unable to conclude that the scienter inference is at least as compelling as any competing inference from the "whole factual picture painted by the [Amended Complaint]." As a result, Plaintiff has not pleaded scienter with the particularity that is required by the PSLRA.

Alberici I at *19. It also noted that, "for some statements, there is no clear theory of falsity, and for others, the applicability of the PSLRA's safe harbors raises legitimate questions about actionability" but did "not engage in statement-by-statement analysis because the insufficiency of the scienter allegations applies to all of the alleged misrepresentations." Id. at *8.[6]

[6] Plaintiff has changed its list of challenged statement in the SAC such that Alberici I guides, but does not mandate, the Court's decision-making here.

Plaintiff filed its Second Amended Complaint on February 24, 2020. ECF 50. In June 2020, Defendants again moved to dismiss. ECF 51 ("Defs.' Br."). Plaintiff opposed, ECF 54 ("Pl.'s Br."), and Defendants replied, ECF 56 ("Defs.' Reply").

IV. Judicial Notice

Defendants request that the Court take judicial notice of twelve documents, arguing each is a relevant public record. Defs.' Br. at 9–11. Plaintiff does not oppose Defendants' Exhibits B through H but opposes notice for Exhibits I through M ("Challenged Documents"), conceding that they are public records but arguing they are not relevant to the current proceedings. Pl.'s Br. at 28–30. The Challenged Documents all concern Recro's appeal of the FDA's May 24, 2018 rejection of IV meloxicam and the FDA's eventual approval of the drug on February 20, 2020. Defs,' Br. at 10–11; Pl.'s Br. at 29–30. In addition to announcing the FDA's approval of the IV meloxicam NDA, Exhibit K includes information from a January 2020 survey in which "approximately 39% of medical doctors believed they will use IV meloxicam in soft-tissue procedures." Defs.' Br. at 27.

"A district court evaluating a motion to dismiss under Rule 12(b)(6) may take judicial notice of . . . matters of public record [but] 'matters extraneous to the pleadings' should not be considered." Alberici I, 2020 WL 806719, at *7 (citing In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1432 (3d Cir. 1997)). The FDA's decision to re-review and subsequently approve IV meloxicam may be relevant to loss causation. See infra Footnote 13 (subsequent approval is relevant but not dispositive). The Challenged Documents are therefore relevant to deciding this motion.

For Exhibit K, however, Defendants' discussion of a January 2020 survey is not relevant to what Defendants knew and misrepresented during the class period that ended over a year and a

half earlier. The Court takes judicial notice of Defendants' Exhibits B through M but declines to take judicial notice of Exhibit K to the extent that it discusses those survey responses.

V. Legal Standard

"In considering a motion to dismiss under Rule 12(b)(6), the Court 'accept[s] all factual allegations as true [and] construe[s] the complaint in the light most favorable to the plaintiff.'" Alberici I, 2020 WL 806719, at *4 (quoting Warren Gen. Hosp. v. Amgen Inc., 643 F.3d 77, 84 (3d Cir. 2011)). But "that requirement does not apply to legal conclusions; therefore, pleadings must include factual allegations [and incorporated information] to support the legal claims asserted." Id. (citing Ashcroft v. Iqbal, 556 U.S. 662, 678, 684 (2009)). "Accordingly, to survive a motion to dismiss, a plaintiff must plead 'factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" Id. (quoting Iqbal, 556 U.S. at 678).

As previously discussed in Alberici I, however, "[a] securities fraud complaint must do much more than a typical complaint," id.; it must also satisfy heightened pleading requirements under the PSLRA:

> In a nutshell, the PSLRA requires that securities fraud complaints specify each misleading statement; . . . set forth the facts on which a belief that a statement is misleading was formed; and . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

Id. at *5 (citations and internal quotation marks omitted).

For the "particularity" requirement, "securities fraud plaintiffs must plead the who, what, when, where and how of the alleged fraud," id., and, if alleged on information and belief, "the

complaint shall state with particularity all facts on which that belief is formed." Id. (quoting 15 U.S.C. § 78u-4(b)).[7]

For the "state of mind" requirement — i.e., scienter — the Court must follow the three-step prescription in Tellabs:

> First, faced with a Rule 12(b)(6) motion to dismiss a § 10(b) action, courts must, as with any motion to dismiss for failure to plead a claim on which relief can be granted, accept all factual allegations in the complaint as true. Second, courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. . . . Third, in determining whether the pleaded facts give rise to a strong inference of scienter, the court must take into account plausible opposing inferences.

Id. at *14 (citing Tellabs, 551 U.S. at 322–23) (emphasis original).

VI. Parties' Contentions

a. Defendants' Arguments

First, Defendants argue that this Court should dismiss Plaintiff's SAC for failure to state a claim under Section 10(b) based on insufficient allegations of scienter. They argue that Plaintiff's allegations are heavily reliant on CW1 and fail to provide the specifics of information-sharing — who knew what, when they learned it, and how — that would create the requisite strong inference that Defendants recklessly or consciously misled investors.

Second, Defendants contend that each of the Challenged Statements is (1) not false or misleading and/or (2) protected under the PSLRA's safe harbor for forward-looking statements. The Court did not rule on this issue in Alberici I. Defendants rely largely on the FDA's subsequent approval of IV meloxicam and on mitigating language within these statements about planned

[7] "The particularity requirement in Rule 9(b) 'is comparable to and effectively subsumed by the requirements of . . . the PSLRA.'" Id. (quoting Inst. Invs. Grp. v. Avaya, Ltd., 564 F.3d 242, 253 (3d Cir. 2009)).

growth into the soft-tissue market — e.g. "we believe," "potential," "target opportunity," and "anticipated." See ECF 56-1 (summarizing statement-by-statement defenses).

Finally, Defendants argue that the Court should reverse its prior conclusion that Plaintiff satisfied loss causation based on new information: the FDA subsequently approved IV meloxicam for hard- and soft-tissue use in February 2020.

b. Plaintiff's Arguments

Plaintiff contests Defendants' scienter arguments by citing to the SAC's expanded allegations regarding CW1's first-person accounts of relaying KOLs' concerns directly and indirectly to the Individual Defendants, arguing that these allegations demonstrate Defendants' awareness of KOL concerns and decision to obscure that information from investors.

For the no-falsity and safe harbor defenses, Plaintiff argues that Defendants had an obligation to disclose KOLs' concerns to correct likely misinterpretation of their statements, making them constructively false or misleading, and that the statements do not fall under the safe harbor of the PSLRA. See ECF 56-1 (summarizing the statement-by-statement challenges).

Plaintiff also argues that the FDA's approval of IV meloxicam nearly two years after the initial denial and the close of the class period is irrelevant to the case's claims, and the Court's prior rulings regarding loss causation and materiality should remain.

VII. Analysis

Defendants assert three main arguments: (1) the SAC does not satisfy the PSLRA's heightened standard for pleading scienter, (2) the individual statements are not actionable because they are either true or protected by the PSLRA's safe harbor for forward-looking statements, and (3) the FDA's subsequent approval of IV meloxicam compels the Court to reverse its prior conclusion that Plaintiff alleged loss causation. The Court disagrees on all three points. For the reasons discussed below, Plaintiff has pleaded sufficient allegations to satisfy all six elements of

its Section 10(b) claim (and, by extension, its Section 20(a) claim); therefore, the Court will deny Defendants' Second Motion to Dismiss.

a. Scienter

For a Section 10(b) claim, the plaintiff must "plead facts that lead to a 'strong inference' of scienter" — i.e. to "deceive, manipulate, or defraud" through "conscious or reckless behavior." Alberici I, 2020 WL 806719, at *14 (quoting Tellabs, 551 U.S. at 313, and Avaya, 564 F.3d at 276). In the SAC, Plaintiff significantly expanded its allegations regarding CW1's practices of informing Defendants about the KOLs' concerns to include the "'who, what, when, where, and how' of the fraud." Id. (quoting Avaya, 564 F.3d at 253). Plaintiff has satisfied its pleading burden for scienter.

As previously stated in Alberici I:

> The pertinent inquiry [for scienter] is "whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." In assessing scienter, courts must "consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." To survive dismissal, the inference of scienter "must be cogent and compelling, thus strong in light of other explanations."

Id. (quoting Burlington, 114 F.3d at 322–24).

Plaintiff alleges that CW1 was, at all relevant times, a member of Recro's Leadership team, whose job included collecting, processing, and transmitting KOL feedback on Recro products for review by Individual Defendants. CW1 informed them that (1) a significant majority of KOLs thought that IV meloxicam was not suitable for soft-tissue use and (2) approximately 30% of KOLs were concerned about insufficient manufacturing oversight in Ireland. Plaintiff's allegations show the details of when and how he directly informed — or witnessed as others informed — each Defendant of these concerns throughout the class period. These pleadings are sufficient.

Taking the allegations collectively, Plaintiff has satisfied its burden in pleading that Defendants were aware of the KOL concerns at issue here but consciously or recklessly obscured those concerns from investors. While Plaintiff may not have provided all the specificity to these allegations that Defendants desire, such additional information can be sought through discovery.

b. Statement Actionability

Defendants argue that (1) none of the Challenged Statements is false and misleading, (2) the SOX Certification is not actionable, and (3) most Challenged Statements fall under the PSLRA's safe harbor for forward-looking statements. The Court previously declined to rule on these issues in Alberici I. 2020 WL 806719, at *8. Now, after reviewing each of the Challenged Statements, the Court disagrees with Defendants' arguments. Plaintiff has pleaded sufficient facts to support the reasonable inference that all eighteen Challenged Statements are false or misleading, actionable, and unprotected by the PSLRA safe harbor.

i. The FDA's 2020 Approval of IV Meloxicam Does Not Affect the Falsity or Materiality Analysis.

As an initial matter, Defendants argue seventeen of the eighteen Challenged Statements (all except for ¶ 95) were not false or misleading because the FDA approved IV meloxicam for hard- and soft-tissue uses in 2020. See Defs,' Br. at 34–38. But approval of the drug almost two years after the end of the class period does not indicate that the statements were not false or misleading at the time they were made. See In re Amarin Corp. PLC Sec. Litig., 689 F. App'x 124, 132 (3d Cir. 2017) (Plaintiff must plead that defendants "did not honestly believe their projections" at the time they were shared because reliance on the FDA's subsequent approval

decision "would amount to pleading fraud by hindsight, something our Court has long rejected.") (citing OFI Asset Mgmt. v. Cooper Tire & Rubber, 834 F.3d 481, 497 (3d Cir. 2016)).[8]

Indeed, Defendants focus on the approval as if Plaintiff's claims arise solely out of the FDA's approval or denial of the drug. This is incorrect. Plaintiff claims that Defendants obscured KOL feedback which, if disclosed to the public, would have reduced the purchase price of Recro shares to an uninflated level. The FDA's actions in 2020 do not obviate Plaintiff's allegations regarding 2017 or 2018, nor do they render any allegedly false statements from that time true.

ii. The Target Opportunity Statements

In the "Target Opportunity Statements" (SAC ¶¶ 82–84, 86–89, 91–93, 97, 100, and 101), Defendants made public statements discussing projected sales in the soft-tissue market (including abdominoplastic, gastrointestinal, and colorectal procedures) using language such as "target opportunity" or "target strategy" for IV meloxicam's sales.[9] Despite touting the potential for profit, however, Defendants allegedly failed to mention KOLs' significant concerns that IV meloxicam would not succeed in that market.

Defendants argue that public statements identifying the soft-tissue market as a target opportunity were not false or misleading, even though "a significant majority" of KOLs, including approximately 75% of those who could set protocols for IV meloxicam's usage at their institutions, warned that the drug was not suitable for soft-tissue use. Defendants contend that there was still some appetite for the drug in the soft-tissue market that made it a "target opportunity."[10] But the

[8] For the same reason, the FDA's subsequent approval of IV meloxicam does not change the Court's prior holding that "Plaintiff has pleaded materiality under Section 10(b)." Alberici I, 2020 WL 806719, at *12.

[9] There are differences within the Target Opportunity Statements, but each has the same relevant contents.

[10] The Court declines to take judicial notice of Defendants' relied-upon "[s]ubsequent independent research." See supra Section IV (Judicial Notice).

possibility of some interest does not change the fact that the statements, as alleged, were misleading: Defendants promised Recro's investors growth in the market while failing to inform them of expert warnings that IV meloxicam would not be well received there. Plaintiff has sufficiently satisfied its burden in pleading that these statements may be false or misleading to survive dismissal.

iii. The Market Frequency Statements

In each of the "Market Frequency Statements" (SAC ¶¶ 94, 98, 102), Defendants stated that "the majority of HCP [health care professionals] surveyed said they would accept IV Meloxicam as a valuable addition upon approval to multimodal pain-management protocols. They estimated they would use the product in ~30% of their surgical cases."[11]

Although Defendants argue that Plaintiffs have not sufficiently alleged that these statements are false, these statements were at least misleading as alleged. Defendants discussed IV meloxicam's marketability but did not disclose that the KOLs voiced significant concerns regarding soft-tissue use of IV meloxicam or that those concerns could seriously impact the marketability of the drug. If Plaintiff's allegations prove true, a jury may reasonably find that the Market Frequency Statements are false or misleading.

iv. The Manufacturing Oversight Statement

The Manufacturing Oversight Statement (SAC ¶ 96) is from Recro's 2017 Form 10-K, stating that Recro's "Acute Care Product Candidates" (referred to in the plural) receive "oversight by our internal managers" (referred to in the plural). Plaintiff alleges that IV meloxicam had only one internal manager, rendering this statement false or misleading. Defendants respond that

[11] ¶ 94 also states that the "core target procedures" include "GI/Colorectal" ones. This statement may be found to be false or misleading for the reasons provided for the Target Opportunity Statements.

the plain reading of this statement applies to multiple products, for which there were multiple assigned internal managers, so the statement was true.

Both parties have offered reasonable constructions of the challenged language. But the determinative issue is what "a reasonable investor would read [the challenged language] to mean." Howard v. Arconic Inc., 395 F. Supp. 3d 516, 544 (W.D. Pa. 2019). Since a reasonable investor certainly could have read "internal managers" to mean there were multiple managers overseeing IV meloxicam, Plaintiff has sufficiently alleged that the Manufacturing Oversight Statement is false or misleading.

v. The SOX Certification

The SOX Certification (SAC ¶ 95) is Defendant Henwood's certification that the 2017 Form 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements . . . not misleading." The 2017 Form 10-K included the allegedly false or misleading Manufacturing Oversight Statement. Defendants argue that this is not actionable because (1) it is a legal conclusion[12] and (2) the internal statement is not false or misleading.

SOX certifications can be actionable where the plaintiff has shown that the signor was attesting to a false or misleading statement with the requisite scienter. See, e.g., Zhengyu He v. China Zenix Auto Int'l Ltd., No. 18-15530, 2020 WL 3169506, at *7 (D.N.J. June 12, 2020) (finding SOX certification actionable); Kanefsky v. Honeywell Int'l Inc., No. 18-15536, 2020 WL 2520669, at *5 (D.N.J. May 18, 2020) (same). Because the Court finds that Plaintiff has pleaded

[12] Defendants failed to assert this argument in their brief, raising it only in the supporting exhibit. While the Court need not address it here, it will do so briefly. See Lord Abbett Affiliated Fund, Inc. v. Navient Corp., 363 F. Supp. 3d 476, 497 (D. Del. 2019) ("The Court will not dismiss the portion of Plaintiffs' claims based on the SOX certifications, because Defendants' only arguments on this issue were buried in a couple of footnotes . . . .").

that the Manufacturing Oversight Statement was false or misleading and that Henwood had scienter, the SOX Certification is actionable. A jury may find that this statement is false or misleading if Plaintiff can demonstrate the truth of its allegations.

vi. PSLRA's Safe Harbor for Forward-Looking Statements does not Require Dismissal.

The PSLRA provides a safe harbor from Section 10(b) liability for a statement that is forward-looking, defined to include "a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer." 15 U.S.C. § 78u-5(i)(1)(B). A forward-looking material statement is protected if it is "identified as a forward-looking statement and is accompanied by meaningful cautionary statements." 15 U.S.C. § 78u-5(c)(1)(A). Defendants argue that the Target Opportunity Statements and the Market Frequency Statements are shielded within this safe harbor.

But the forward-looking statement protection does not "apply to statements challenged on the basis that they omitted 'present facts' — facts known at the time the statement was made." Marsden v. Select Med. Corp., No. 04-4020, 2006 WL 891445, at *7 (E.D. Pa. Apr. 6, 2006) (Joyner, J.); see also In re Viropharma Inc. Sec. Litig., 21 F. Supp. 3d 458, 471 (E.D. Pa. 2014) (Jones, II, J.) ("Courts in this District have held that omissions of existing facts or circumstances are not forward-looking, and thus do not qualify for safe harbor protection."). As alleged, Defendants made forward-looking statements about IV meloxicam's prospects in the soft-tissue market that were incompatible with Defendants' then-current knowledge of KOL feedback. Based on these allegations, the Court cannot agree with Defendants' argument that safe harbor protection mandates dismissal of Plaintiff's claims regarding the Target Opportunity Statements or Market Frequency Statements.

c. Loss Causation

The Court previously ruled that Defendants' actions, as alleged, caused investors to purchase Recro stocks at inflated prices. See Alberici I, 2020 WL 806719, at *14 ("the omission increased the market's estimation of the likelihood of FDA approval for soft-tissue uses, and therefore the stock price"). After the corrective disclosure in May 2018, the stock price fell. Id. This satisfied Plaintiff's burden for loss causation. Id.

Defendants argue now that the FDA's subsequent decision to approve IV meloxicam undermines the Court's prior finding, but that is incorrect. The May 2018 drop in Recro shares came from two negative impacts: the FDA's denial and the corrective disclosure. The FDA's 2020 decision affects discussion of the former, but does not negate the existence of the latter.[13] See In re Urban Outfitters, Inc. Sec. Litig., 103 F. Supp. 3d 635, 655 (E.D. Pa. 2015) (Restrepo, J.) ("disclosure of the alleged fraud need not be the sole reason for the depreciation of the stock price") (citing In re Cigna Corp. Sec. Litig., 459 F. Supp. 2d 338, 349 (E.D. Pa. 2006)). The Court sees no reason to change its prior conclusion that Plaintiff has demonstrated loss causation for the purposes of this Rule 12 motion, although "whether Plaintiff can ultimately establish loss causation [at trial] is an entirely different question." Alberici I, 2020 WL 806719, at *14.

VIII. Conclusion

For the reasons set forth above, the Court DENIES Defendants' Second Motion to Dismiss. An appropriate Order follows.

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[13] The FDA's February 2020 decision to approve IV meloxicam may be relevant to how much the FDA's initial denial affected the price drop but not how much the corrective disclosure reflected an inflated market price. Later loss causation arguments in this case will likely debate how much of the price drop came from each of these two sources. The eventual IV meloxicam approval is therefore relevant but not dispositive to the issue of loss causation.